

Patent Claims

- 1) A composition comprising 0.001 to 3% of tiotropium, or a pharmaceutically acceptable salt thereof, in admixture with a physiologically acceptable excipient
5 having an average particle size of 10 - 50 μm , a 10 % fine content of 0.5 to 6 μm and a specific surface of 0.1 to 2 m^2/g .
- 2) The composition according to claim 1 wherein the tiotropium is present as a salt in the form of the chloride, bromide, iodide, methanesulphonate or para-
10 toluenesulphonate.
- 3) The composition according to claim 1 wherein the physiologically acceptable excipient is selected from the group consisting of the monosaccharides, disaccharides, oligo- and polysaccharides, polyalcohols and salts, and combinations
15 thereof.
- 4) The composition according to claim 3 wherein the physiologically acceptable excipient is selected from the group consisting of glucose, arabinose, lactose, saccharose, maltose and trehalose, optionally in the form of the hydrates thereof,
20 and combinations thereof.
- 5) A method for preparing a pharmaceutical dosage form for treating respiratory disease, COPD and/or asthma comprising introducing the composition according to claim 1 into a capsule suitable for delivery of the composition to a patient by
25 inhalation.
- 6) A capsule containing the composition according to claim 1 in powder form.
- 7) The capsule according to claim 6 consisting essentially of one or more synthetic
30 plastics.

- 8) The capsule according to claim 7 wherein the synthetic plastic is selected from the group consisting of polyethylene, polycarbonate, polyester, polypropylene and polyethylene terephthalate, and mixtures thereof.
- 5 9) A capsule suitable for delivering a composition to a patient by inhalation comprising about 1 to 20 mg of the composition according to claim 1.
- 10) An inhalation kit comprising the capsule according to claim 6 and an inhaler which can be used for administering inhalable powders from powder-filled capsules.
- 10 11) The inhalation kit according to claim 10 wherein the inhaler comprises a housing containing two windows, a deck in which there are air inlet ports and a screen secured via a screen housing, an inhalation chamber connected to the deck on which there is a push button actuating two sharpened pins and movable counter to a spring, a mouthpiece which is connected to the housing, the deck, and a cover via a spindle to enable it to be flipped open or shut, and airholes for adjusting the flow resistance.
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